EXHIBIT C

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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CITIZENS FOR CONSUMER JUSTICE, et al Plaintiffs,
vs.
ABBOTT LABORATORIES, et al Defendants.
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CIVIL ACTION
No. 01-12257-PBS

BEFORE THE HONORABLE MARIANNE B. BOWLER
UNITED STATES MAGISTRATE JUDGE
MOTION HEARING

A P P E A R A N C E S

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September 27, 2004
10:30 a.m.

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P R O C E E D I N G S

THE COURT: Please be seated.

THE CLERK: Today is Monday, September 27, 2004. The case of Citizens for Consumer Justice, et al versus AbbotT Laboratories, et al. Civil action No. 01-12257 will now be heard before this Court.

Would counsel please identify themselves for the record.

MR. SOBOL: Good morning, Your Honor. Tom Sobol, Hagens Berman, for the plaintiffs.

THE COURT: Thank you.

MR. KODROFF: Jeffrey Kodroff, Spector, Roseman & Kodroff, also for the plaintiffs.

MR. WEXLER: Ken Wexler, Your Honor, the Wexler Firm, for the plaintiffs.

MR. THEODOROU: Nicholas Theodorou, Your Honor, for the defendants.

MR. HOBART: Geoffrey Hobart, Your Honor, Holland & Knight, for the defendants.

MS. HARRIS: Kim Harris, Your Honor, from Davis Polk & Wardwell, representing AstraZeneca Pharmaceuticals.

MR. EDWARDS: Steven Edwards, Hogan & Hartson, Bristol-Myers Squibb.

MR. MORGENSTERN: Saul Morgenstern, Kaye

Scholer in New York, for Novartis Pharmaceuticals.

MS. GREEN: Karen Green, Wilmer Cutler Pickering Hale and Dorr for Novartis Pharmaceuticals.

MR. RILEY: Your Honor, my name is Richard Riley. I represent First DataBank, Incorporated and Kay Morgan who are non-parties and have a motion to be heard before you, Your Honor, this morning.

This (indicating) is David Schulz who is going to argue pro hac vice for First DataBank.

THE COURT: All right. You may want to sit at that table then.

MR. TRETTER: And last but not least, Your Honor, Lyndon Tretter from Hogan & Hartson, for Bristol-Myers Squibb.

THE COURT: Thank you very much.

MR. SOBOL: If I may, Your Honor, I have conferred with counsel and we have a schedule of the motions to go through. I'd like to provide a road map of the, at least the order of the motions that relate to us, unless the Court has --

THE COURT: I have my own road map.

MR. SOBOL: That's why I am asking first.

THE COURT: Well, let me just tell you a few things at the outset.

It is my practice in handling discovery matters to

make as many decisions as possible from the bench. If I take things under advisement, they take their place in the order of other matters that I have and then you will have to wait for a ruling. So it would be my determination here today to make all the rulings from the bench.

There may be certain times that I deem it appropriate to take a recess, go off, look at something and come back.

The whole day is available to you. We will go until one o'clock and then break from one to two and if need be come back. And I will take a brief recess mid morning.

But I have gone through all the motions and fashioned them out in a manner that I think makes sense. There were a few things that were not noticed in the notice that was sent out by the clerk and there also have been some motions that have come in since then that it might be appropriate to deal with at this time.

So it would be my fashion to take them in the order in which they were filed. So I would start with docket entry No. 884, which is plaintiffs' motion to compel.

Do you have dockets in front of you, printed dockets?

MR. SOBOL: I don't, Your Honor.

THE COURT: Well, it is really helpful to do that before you come here. The night before the morning of

court to print the final docket, the last, in this case probably one hundred or so docket entries so that you can see everything and see exactly what it is we are dealing with.

All right. That's 884, which is plaintiffs' motion to compel the production of HHA ASP documents relating to all defendants. All right.

MR. SOBOL: That actually was first on our list.

THE COURT: Of course, Mr. Theodorou.

MR. SOBOL: Before I address the motion, Your Honor, I'd like to report that I think that there is -- the parties agreed to an agreement with respect to the McKesson motion. And I believe that there is counsel from McKesson who might be here in the courtroom so rather than having him or her sit around, I just wanted to report that.

And unless the Court had any questions about it, I think that the matter was going to be taken care of --

THE COURT: He is well known, Counsel.

MR. KIERNAN: Good morning, Your Honor. John Kiernan on behalf of McKesson Corporation. And it's my understanding as well that that's been withdrawn.

THE COURT: And, of course, you can't tell me the docket number; can you?

MR. SOBOL: I will momentarily, Your Honor.

THE COURT: Does anyone have a docket? Amazing.

MR. KIERNAN: Thank you, Your Honor.

THE COURT: You are excused, Mr. Kiernan.

MR. KIERNAN: Thank you.

MR. SOBOL: Your Honor, the briefing on the plaintiffs' motion to compel the HHA ASP documents is briefed in this modern day --

THE COURT: Just one moment. If I can see the law clerk for a second.

(Whereupon, the Court and the Clerk conferred.)

THE COURT: As to the McKesson motion, if you can file a letter with the Court indicating what docket entry that was and that it was withdrawn in open court.

MR. KIERNAN: I will do so immediately, Your Honor.

THE COURT: All right. Thank you, Mr. Kiernan. And you are excused if you don't want to stay.

MR. KIERNAN: Thank you, Your Honor.

THE COURT: All right.

MR. SOBOL: Thank you, Your Honor.

I'd like to address the plaintiffs' motion to compel the HHA ASP documents. The briefs are relatively short and so my argument is also going to be intended to be relatively short.

It's important to place the motion in the context of the case of course as a whole. The case ultimately involves a question as to the extent to which the reimbursement rates posted by the defendants in the context of AWP are an abuse of a variety different systems. Whether they're an abuse of Medicare Part B or whether they're an abuse of reliance of the private reimbursement system for oral pharmaceuticals or for the injectables.

Now, there are disputed issues of fact that the parties heatedly have on those matters. One of them is, for instance, has there been a difference between the actual selling prices in the variety of publicly published pricing points, whether it's AWP or the wholesale acquisition cost, the WAC.

It's also a question about whether or not the actual selling prices have been different than other price points that aren't publicly available. For instance, the average manufacturer price or the AMP.

So the extent to which there is a difference between the actual selling price and the posted price is critical to the case. But the motion seeks to have the defendants compel what they are currently reporting for average selling prices for what the, what we call AWPID, or average wholesale price inflated drugs. Those are the drugs that are the core obviously of the case itself.

Now, if I understand the defendants' argument, it is essentially that, well, what we are doing now is either too complex or, you know, not really refined right now and it's not going to be relevant. And we say that that's not true for the following reasons.

First, whether it is practical or not to publish ASPs or to more closely publish reporting prices that more closely reflect the actual transaction cost, whether that's a practical possibility or not is a dispute. And so if we can show what they do right now is something that they can practically do, then that is relevant for us to get the ASPs.

Second, the complaint seeks injunctive relief in addition to monetary relief for current wrongdoing. So to the extent to which they are now reporting certain things may be used by the defendant, likely will be used by the defendant as a defense, that it is not necessary to order injunctive relief. But obviously we would need to know the kinds of things that they are actually reporting in order to find out whether it's necessary or not.

Third, there is a big issue that the defendants make -- and I think you will see this in a variety of other motions we have here -- as to what exactly should the AWP have been or what is it that an ASP really is. And I think there are many complicated subsidiary issues in that

question that they are currently right now trying to iron out with HHS and with CMS.

Well, obviously their position that they're taking with respect to those miscellaneous issues, what's inside or outside the calculation of ASP, goes directly to their questions about what we should be doing and what kind of arguments we should be making. So it's relevant again for us to get that kind of information.

Also the argument really is simply a relevancy question. It's not a question of burden because obviously the information is information that they have readily available so it is current so it's nothing that they have to go back into the archives to be able to retrieve that kind of thing.

To the extent that it's confidential -- and it may be confidential to some extent -- this Court already has pending orders that protect the confidentiality of the material also.

And ultimately, this really is the bottom point, to the extent that they think it's not a final number but it's something that needs to be discussed and refined more and more, and they have a dialogue with CMS on that, that's precisely all the more reason why this is exactly the kind of information that would be helpful to have for this case. To know what they claim the nuances are to these, what the

impracticalities are from their point of view that they're representing to the federal government are helpful.

So it goes not only to monetary relief but also to injunctive relief when we get to the core about the practicality and the content of reporting actual prices, Your Honor.

THE COURT: Mr. Hobart.

MR. HOBART: Thank you. Your Honor.

Mr. Sobol's two central points as to relevance, Your Honor, I'd like to rebut very directly.

One, with respect to the average selling price, interim and proposed final regulations that came out in September, the defendants' position has been and is that that guidance is a moving target. That's point No. one. And I'll explain that in a little bit more detail in a minute.

Point No. two, Your Honor, is that the average selling price requirement deals with quarters that are not at issue in the plaintiffs' amendment consolidated complaint at all.

THE COURT: What is your response to that?

MR. SOBOL: Twofold, Your Honor.

First, what they're doing today goes directly to the question of injunctive relief today. So regardless of whether or not -- we can't have an injunction for past

conduct. Obviously an injunction seeks to protect current and future conduct, No. one.

No. two, what someone is doing today can create an inference about what occurred previously. So what the average selling price differences are today against posted prices might create an inference regarding what those prices had been in the past.

THE COURT: Might.

MR. SOBOL: Might. I'm not saying that they will. But, again, it's discoverable information we suggest.

MR. HOBART: And again, Your Honor, the defendants are well aware of the liberal discovery standard. But we are here today to demonstrate to the Court that even under that liberal standard there is no possibility that this information is relevant to injunctive relief or any other issues in this case.

This is not a situation, Your Honor, where the companies have not provided the plaintiffs with the data, the transaction level data that they need to perform historical average selling price model if they choose to do that as part of their case.

This is, I think, you know, I'm well aware that the Court has extensive background with hospitals and medical issues so I won't -- I'll assume you have knowledge about that.

But the Medicare reimbursement system has evolved over time to -- since 1991 as reflected in the papers.

The average wholesale price is the concept. It's not defined anywhere. No pharmaceutical company has ever been required to report an average wholesale price to any government entity or third party acting on behalf of it or contracted by the government.

The history itself as this has evolved needs to be compared and contrasted to some other reimbursement systems that were in place. For example, for Medicare when Congress initially extended coverage to certain drugs in an outpatient setting, the so-called Medicare Part B, the legislation suggested or directed HCFA to reimburse at the doctor's actual charge or pursuant to a fee schedule to be resolved by HCFA.

HCFA then proposed a rule that the payment for the drugs should be at 85 percent of the national AWP.

The oncologists and the lobbyists, you know, went to work and demonstrated to Congress and to HCFA that that was an inadequate level of reimbursement for the oncologists and other doctors.

And that final regulation that came out in 1991 provided for reimbursement to be the lesser of one hundred percent of AWP, or estimated acquisition cost as determined by surveys conducted by the Medicare carriers.

Those surveys, Your Honor, were never feasible or completed and the reimbursement rate 1991 to 1997 was one hundred percent of AWP.

Now, the irony and the reality here is that was the reimbursement rate. But the companies were never required to report to the government or anybody else --

(Whereupon, the Court and the Clerk conferred.)

MR. HOBART: -- about an AWP for a product. And this practice the way the AWPs were derived and used by the Medicare carriers for reimbursement, as a general proposition, companies would report a wholesale price, either wholesale acquisition cost or net wholesale price to three price reporting services: Red Bank -- Red Book, First DataBank and Medi-Span.

Those price reporting services would apply a multiplier, either at 1.2 or 1.25, to derive AWP which they publish in their catalogs for use by the Medicare carriers in establishing reimbursement rates.

So in terms of what the companies were reporting or required to report, there was no requirement. And as a matter of practice, it was the wholesale price that was reported to these price reporting services.

Now, different from the AWP, Medicare AWP reimbursement system, in 1991 the Congress also enacted the Medicaid Rebate Statute which did have very clear reporting

requirements for the companies. They defined a number of the terms, "average manufacturer's price" or AMP, A-M-P as Mr. Sobol just referred to was one benchmark which is essentially the price charged to wholesalers for sale to the retail pharmacy class trade less the prompt paid discount.

A "best price," which is the lowest price charged by a company to certain purchasers.

And then the state would be entitled to rebates based on the difference between AMP and best price or the lower or that was -- or the greater of the 15.1 percent. So it's either 15.1 percent of AMP or the delta between AMP and best price with adjustments for a cost of CPI penalty if applicable.

So you have two situations, two different programs with two entirely different sets of rules of the road.

In this case the plaintiffs have asked for the production of AMP data. And the defendants have not objected to that. And I believe every defendant who has received such a request has complied with that.

And the reason we complied with that is, one, the AMPs are calculated for the relevant time periods that are at issue in this case. And it's pursuant to established regulations and definitions that have become established over time.

Different from the average selling price, you know,

the model that just recently was enacted and is still under evolution.

Now, the AWP reimbursement system stayed at one hundred percent AWP from '91 to '97. There was a fair amount of legislative attention to the high cost of Medicare drugs during that time period. And I won't go into all the details, but the Clinton Administration made a number of proposals to change the reimbursement benchmark from Medicare, the actual acquisition cost or some percentage off of AWP.

And in 1997 on the Balanced Budget Act of 1997 a change was implemented to 95 percent of AWP. And from 1997 to literally 2003 there has been an enormous amount of legislative attention, lobbying efforts by oncologists and others in this political process about what the appropriate reimbursement rate has been.

And there has been a number of proposals, '98, '99, 2000 including in the year 2000 now Attorney General Ashcroft introduced a bill to freeze any changes in the Medicare reimbursement rate by HCFA until a study can be completed.

And in a speech from the Senate floor he acknowledged that the reason for the potential for oncologists to make a profit off of drugs and the difference between their acquisition cost and the AWP was in order to

adequately compensate oncologists for other services that are rendered in outpatient cancer clinics that are inadequately compensated under the various fee schedules by HCFA, now CMS.

So I understand the plaintiffs' theory, Your Honor -- but it's a lot more complicated than that -- there is the political process at work here. It's been at work for over twelve years. And that process finally in the year 2000 produced a change in the reimbursement structure for Medicare.

In December of 2003 the Medicare Modernization Act was passed. That act changed the benchmark from the AWP model, the Medicare reimbursement benchmark to an average selling price.

What they didn't -- Congress did not flesh out that definition in any, you know, meaningful way that can be applied in practice. It's an average selling price of purchases or sales to U.S. based purchasers net of what had come to be known as price concessions, discounts, rebates or other items of value, and excluding purchases to otherwise exempt purchasers of the federal supply schedule and folks like that.

Under the Medicare Modernization Act the companies are required to begin reporting ASP to -- the ASP numbers by NEC number to CMS beginning the first quarter of 2004. So

the first submission was 30 days after the close of the quarter on April 30th.

There has been another submission for the second quarter in July. The CMS issued proposed interim regulations on April 6. One of the points the defendants make in their papers is that these proposed regulations in a question/answer form that was conducted made it very clear that there are a number of moving parties to this regulation in terms of trying to implement how an average selling price would actually be calculated or reported to the federal government.

One of the key issues that drew a lot of attention from people in the industry was the issue of the lag in reporting time. Just in two minutes on pharmaceutical drug pricing, Your Honor, I think it would be useful to put this into context.

Most pharmaceutical companies have very few direct sales to their end customers. In terms of distribution the company sells their products to wholesalers. Wholesalers in turn sell the products to the end users, in this case in particular oncologists.

And then the companies also have contracts, typically have contracts with a number of their end user customers. But because they're not delivering the product to the customers, there is a mechanism in place to make sure

that the end customer gets the price they contracted for, that that system is administered by the wholesalers.

So, for example, if the contract price is for one hundred dollars to an end user, and the price to the wholesaler is $120, the wholesaler would have the contract information loaded into its computer system and would give the benefit of the bargain to the oncologist.

But the wholesaler who bought that drug for $120 and is selling it to the oncologist for $100, to make that wholesaler whole they charge the company back the difference, the $20. That's a charge back.

A "charge back" is a term of art really. It's describing the way in which discounts to end users are administered through the wholesale distribution process.

So in terms of calculating an average selling price, it's important to take into account charge backs and discounts. A lot of contractual relationships involve what's known as rebates or market share performance rebates.

So if a contract is for a year and you need to sell, purchase so much of a drug to get like a rebate at the end of the year, you won't know what that rebate is until the contract is completed and the final tally can be done of what was actually purchased.

So to deal with this lag issue initially CMS proposed that the company take a twelve month look back.

They aggregate by NDC the total amount of price concessions for that twelve months and then divided that number by four to get you an absolute number for that quarter. And then to back out that number from the gross sales price to get an approximation of the net gross sales for that quarter for that NDC to divide the units into that numerator.

As the period went forward, one of the things that a number of the commentators and industry groups noted that that created the possibility for negative ASP numbers. By using an absolute number instead of a fraction, a rolling average, that created the possibility that if there were a lot of rebates in a particular quarter and not as many sales to match those up against, the numerator could actually be a negative number producing a negative ASP.

Very recently, and I have a copy of the Federal Register, Your Honor, it came out September 16th, if the Court would take it?

THE COURT: Do you have a copy for your brother?

MR. HOBART: I do.

CMS noticed -- this is the proposed -- the final rule that come out on September 16, 2004, just a couple of weeks ago.

And as the defendants predicted in their original paperwork, Your Honor, that this whole process is a moving

target. CMS changed the way in which the lag should be accounted for. So rather than doing the math the way they proposed in the interim regulations, now a fraction is going to be computed based upon the total price concessions versus the total sales for a 12 month period. For example, it gives an example on the second page.

THE COURT: I see.

MR. HOBART: That percentage will be applied to the sales for a quarter for a product deriving a net sales figure in order to provide a more even way of accounting for the discounts that exist in the field.

The net effect of that, Your Honor, however, is that the submissions that the company made to CMS in April and July are now totally meaningless because the methodology has completely changed with respect to this all important issue.

The other point, in addition to the moving target piece, Your Honor, we are only talking about the quarters that are currently at issue. All the companies are provided to the plaintiffs. All the transaction level data that they need for the time period covered by the amended master consolidated complaint, the charge back data, rebate data, sales level data, it's now -- the challenge for the plaintiffs is how do you aggregate or match up the discount rebates in order to come up with a net price per unit to do

their own average selling price model.

The guise that's in their proposed regulations and what the companies are doing now is not going to be helpful to the plaintiffs at all in terms of performing those types of calculations.

If I could give the Court just one real world example of why that would not be helpful to the plaintiff, and taking the company that I represent Glaxosmithkline as the example.

One of the drugs at issue for Glaxosmithkline is an antiemetic drug called Zofran. It was developed in 1991 by Glaxo Inc. Glaxo, Inc. merged with Barlows Wellcome in 1995 to create Glaxo Wellcome, Inc. And the end of 2000 Glaxo Wellcome, Inc. merged with SmithKline Beecham Corporation to form GlaxoSmithKline.

Each one of those mergers involved the aggregation of Legacy Computer Systems in assembling and merging different assumptions and reporting to the point where after the merger in 2000 GlaxoSmithKline was not able to make one integrated report under the Medicaid Rebate Statute until the first quarter of 2003.

So now that there is an integrated computer system for GlaxoSmithKline for which these average selling price calculations are being currently performed is not going to be any help at all to Mr. Sobol and the rest of the

plaintiffs' lawyers in trying to figure out what the Legacy system for Glaxo Wellcome looked like in 1997 or what the Legacy computer system handling discounts, rebates and charge backs, et cetera, for SmithKline Beecham Corporation during the same time period.

Now, the plaintiffs have recently noticed 30(b)(6) depositions of GlaxoSmithKline and other companies to help them understand the data that the companies have provided to them over the course of the summer. And I suggest to the Court that that's exactly what the plaintiffs should be doing if they want to understand the transactional level data that's already been provided to them or for the relevant time periods.

With respect to the current time periods that are after the filing of the amended consolidated complaint, when you're talking about regulations that are sure to be changed again -- and I call the Court's attention to the first page of the proposed regulations that came out on September 16th, the top right-hand corner -- I'm sorry -- it's the middle column, very top. It's, "Other issues and comments relating to interim final rules will be addressed in the future time."

So at the very real world, Your Honor, these regulations are going to change again and again and again. There are a number of ambiguities, inconsistencies that need

to be resolved.

The agency received 79 sets of comments. They're under the gun. They're dealing with this, you know, one quarter at a time for the beginning of ASP reimbursement which starts in the year 2005.

For all these reasons, Your Honor, there just isn't any possibility that what the companies are doing struggling with today to comply with the moving target is going to be of any help at all to Mr. Sobol. They have the tools to deal with the data that's already been provided to them. They have indicated they are prepared to attempt to understand that in deposition and that is sufficient.

THE COURT: A brief reply.

MR. SOBOL: Yes, Your Honor.

I think that I have heard the following points:

The first, a recantation of the pharmaceutical industry's view of history regarding reimbursements and how that's essentially a defense to the case as a whole.

That has been rejected twice already by Judge Saris. She has sustained allegations that there has been an abuse of Medicare Part B systems, that there has been an abuse of the private reimbursement system and that, therefore, getting to the core of what the actual prices have been in order to demonstrate the extent of the abuse is something that is completely within the target of discovery

in this case.

Second, in terms of there being a time lag or not, that's precisely why it is we need the information. All the representations that have just been made to you are not grounded in any kind of record.

So what do I mean by that? Well, the representation that ASP as promulgated by the Modernization Act doesn't, quote, in any meaningful way, end quote, define ASP.

We disagree. We think it does define in a meaningful way. The fact that there was a HCFA regarding how it is that you roll back over time the charge backs and the rebates and how that was able to be ironed out within a short period of time demonstrates to us quite frankly that we think that the information we will get, that we get this information provided to us, is that the industry actually thinks that this is something that is doable. It's completely doable.

There are going to be some issues regarding how it is you might time wise roll things up or whether or not certain kinds of payments to PBMs would or wouldn't be a part of the thing.

But all of that goes to show I think really that if the information is provided, we'll be able to get some sunshine as to what the actual reaction has been to the

industry of having to do something which we have said has been practical all along, which the industry said was completely impractical, not realistic until Congress came along last year and said you must do this. And all of a sudden we think that, you know, the information will be able to demonstrate that.

I think at bottom really what the defendants' argument boils -- oh, and then whether or not the information is a moving target or not, whether it's totally meaningless or not. We will only know if we receive the information. Otherwise we will have to be told it's totally meaningless, trust us.

And at bottom really I think the defendants' argument is, plaintiffs, you will be wasting your time if we give you this information.

I really think it's our obligation to make a judgment based upon the information that it's going to be a waste of our time, not to have the defendants make that judgment for us.

THE COURT: Well, at this time I find the request is really too attenuated so the motion is denied.

Now, in light of that motion, there was another related motion which is docket number 868 which was not noticed. And that is Track One Defendants' motion for protective order. So in light of the denial that should be

allowed. All right.

The next matter is docket entry number 888 which is the defendant Bristol-Myers' motion to compel.

MR. EDWARDS: Your Honor, once again, Steve Edwards, Hogan & Hartson, on behalf of Bristol-Myers Squibb.

This is a classic situation in which the defendants are trying to pin down the plaintiffs as to their theory of the case. And the plaintiffs don't want to be pinned down.

The plaintiffs allege that the defendants report AWPs to the publications such as First DataBank, Medi-Span and Red Book. They allege that these AWPs are used by payers to determine reimbursement.

They allege that the defendants sell drugs at prices below the reported AWPs. And as a result there is a spread between the reported AWPs and average sales prices or what the plaintiffs refer to as ASPs.

And they allege further that the spread is marketed and manipulated by the defendants in some way.

So we posed a series of very simple interrogatories to the plaintiffs. We asked them, first of all, what do you contend the proper definition of "AWP" should be.

Secondly, do you contend that the existence of a spread in and of itself violates the law or is there some other act or conduct required in addition to the spread to give rise to a violation.